17 January 2017
EMA/CVMP/35323/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 6-8 December 2016 meeting

Chair: D. Murphy – Vice-chair: H. Jukes

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. CVMP delegates' list of intended participation and identified interests

The attendance list was completed and competing interests were identified for the December 2016 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

iii. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

iv. Adoption of the minutes of the previous meeting

The minutes of the November 2016 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- The Committee noted a request from the applicant to reschedule the oral explanation for the application for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/004333/FULL/0001). The request was agreed in principle.
- The Committee agreed to the request from the applicant for a further extension to the clock-stop for the application for the establishment of MRLs in porcine species for a substance (EMEA/V/MRL/004113/FULL/0001).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by majority (31 members in favour out of the 32 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **EQUIOXX** (EMEA/V/C/000142/X/0015), recommending the extension of the marketing authorisation to add a new pharmaceutical form (chewable tablets for oral use) to an anti-inflammatory product for alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness for horses. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. K. Baptiste and the Icelandic CVMP member signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (32 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Stronghold Plus** (EMEA/V/C/004194/0000), recommending the granting of a marketing authorisation. Stronghold Plus is an antiparasitic product for cats with, or at risk from, mixed parasitic infestations by ticks and fleas, lice, mites, gastrointestinal nematodes or heartworm. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for **RESPIPORC FLUpan H1N1** (EMEA/V/C/003993/0000), recommending the refusal of the granting of a marketing authorisation. RESPIPORC FLUpan H1N1 is a new inactivated viral vaccine with a proposed indication for active immunisation of pigs from the age of 56 days onwards against swine influenza caused by pandemic subtype H1N1. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the updated scientific overview and list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new antiparasitic product for dogs (EMEA/V/C/004247/0000). The Committee agreed that an oral explanation would not be requested, and noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the updated scientific overview and list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new product for cattle (EMEA/V/C/004099/0000). The Committee agreed that an oral explanation would not be requested, and noted three peer review reports and the comments received from CVMP members.
- The Committee adopted the updated scientific overview and list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new product for dogs (EMEA/V/C/003939/0000). The Committee agreed that an oral explanation would not be requested, and noted two peer review reports and the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview and list of questions and agreed comments on the draft product information for a new antiparasitic product for honey bees (EMEA/V/C/002836/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview and list of questions and agreed comments on the draft product information for a new antiparasitic product for chickens (EMEA/V/C/004344/0000). The Committee noted two peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee agreed to the request from the applicant for a 3-month extension to the clock-stop for a new anti-inflammatory product for dogs (EMEA/V/C/004222/0000).

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II variation for **Aivlosin**

(EMEA/V/C/000083/II/0067/G), recommending the variation of the marketing authorisation to implement quality changes. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Broadline** (EMEA/V/C/002700/II/0011), recommending the variation of the marketing authorisation to implement quality changes and changes to the SPC. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

3.3 Lists of questions

- The Committee adopted the list of questions for a grouped type II variation for **ProZinc** (EMEA/V/C/002634/II/0010/G) concerning quality changes.
- The Committee adopted the list of questions for a grouped type II variation for **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/II/0004/G) concerning quality changes.
- The Committee adopted the list of questions for a grouped type II variation for **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/II/0005/G) concerning quality changes.
- The Committee adopted the list of questions for a type II variation for **Broadline** (EMEA/V/C/002700/II/0013), to add new therapeutic indications.
- The Committee adopted the list of questions for a grouped type II variation for **BTVPUR** (EMEA/V/C/002231/II/0008/G) concerning quality changes.

3.4 Re-examination of CVMP opinions

- The Committee agreed to the request from the MAH for the re-examination, in accordance with Regulation (EC) No 726/2004, of the CVMP opinion adopted at the November 2016 CVMP meeting for a type II variation for **Trifexis** (EMEA/V/C/002635/II/0008), to add a new therapeutic indication associated with *Angiostrongylus vasorum* and to extend the treatment duration to infinite treatment. The Committee appointed a rapporteur, and a co-rapporteur. The Committee agreed to the applicant's request for the involvement of an ad hoc expert group (AHEG). The submission of the detailed grounds for the re-examination is foreseen by 9 January 2017. The adoption of the opinion is foreseen for the February 2017 meeting of the Committee.
  Post-meeting note: the request for re-examination was subsequently withdrawn by the marketing authorisation holder.

3.5 Other issues

- There were no items for discussion.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Girolan and its associated name Apralan** (EMEA/V/A/122). The Committee adopted the list of outstanding issues for the marketing authorisation holders to address in writing, the draft product information and the revised timetable for the procedure.

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing zinc oxide to be administered orally to food producing species** (EMEA/V/A/118), recommending the refusal of the granting of the marketing authorisations and the withdrawal of the existing marketing authorisations for veterinary medicinal products containing zinc oxide. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee discussed the letter from aniMedica GmbH and endorsed the CVMP response letter.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses** (EMEA/V/A/116). The Committee adopted the list of outstanding issues for the applicants and marketing authorisation holders to address in writing, and the revised timetable for the procedure.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted concerning recommendations for **FORTEKOR PLUS** (EMEA/V/C/002804/REC/008-009).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **ZOLVIX** (EMEA/V/C/000154/REC/012).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 11.11.2016 – 08.12.2016:

Product	Period
DRAXXIN (EMEA/V/C/000077)	11/11/2015 – 10/11/2016
Meloxivet (EMEA/V/C/000124)	14/11/2015 – 13/11/2016
Porcilis AR-T DF (EMEA/V/C/000055)	16/11/2015 – 15/11/2016
Masivet (EMEA/V/C/000128)	17/11/2015 – 16/11/2016
Meloxoral (EMEA/V/C/000151)	19/11/2015 – 18/11/2016
Easotic (EMEA/V/C/000140)	20/11/2015 – 19/11/2016
Equip WNV (EMEA/V/C/000137)	21/11/2015 – 20/11/2016
Stronghold (EMEA/V/C/000050)	25/11/2015 – 24/11/2016
Oxyglobin (EMEA/V/C/000045)	29/11/2015 – 28/11/2016
Broadline (EMEA/V/C/002700)	04/12/2015 – 03/12/2016
Quadrisol (EMEA/V/C/000032)	04/12/2015 – 03/12/2016
Vectra 3D (EMEA/V/C/002555)	04/12/2015 – 02/12/2016
Contacera (EMEA/V/C/002612)	06/12/2015 – 05/12/2016

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee received a progress report on the PhVWP-V anti-parasitic sub-group activities and noted that the Committee would be informed of the outcome following conclusion of the exercise – *see also 7.8*.
- The Committee endorsed the rapporteur's assessment report on the PSUR for the period 01.03.2016 – 31.08.2016 for **Bravecto** (EMEA/V/C/002526), which included a list of questions to be addressed by the marketing authorisation holder.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.06.2013 – 31.05.2016 for **Easotic** (EMEA/V/C/000140) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 11.08.2013 – 10.08.2016 for **Loxicom** (EMEA/V/C/000141) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.08.2015 – 31.07.2016 for **Rheumocam** (EMEA/V/C/000121) with a recommendation to amend the SPC.

- The Committee adopted the following CVMP assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
ECOPORC SHIGA (EMEA/V/C/002588)	01.08.2015 – 31.07.2016
ERYSENG (EMEA/V/C/002761)	01.02.2016 – 31.07.2016
ERYSENG PARVO (EMEA/V/C/002762)	01.02.2016 – 31.07.2016
Innovax-ILT (EMEA/V/C/003869)	01.02.2016 – 31.07.2016
Kexxtone (EMEA/V/C/002235)	01.08.2015 – 31.07.2016
NEXGARD SPECTRA (EMEA/V/C/003842)	01.02.2016 – 31.07.2016
Porcilis PCV ID (EMEA/V/C/003942)	01.03.2016 – 31.08.2016
ProZinc (EMEA/V/C/002634)	01.08.2015 – 31.07.2016
Suvaxyn PCV (EMEA/V/C/000149)	01.08.2015 – 31.07.2016
UpCard (EMEA/V/C/003836)	01.02.2016 – 31.07.2016
Versican Plus L4 (EMEA/V/C/003680)	01.02.2016 – 31.07.2016
Versican Plus Pi (EMEA/V/C/003681)	01.02.2016 – 31.07.2016
Versican Plus Pi/L4R (EMEA/V/C/003682)	01.02.2016 – 31.07.2016
ZACTRAN (EMEA/V/C/000129)	01.02.2016 – 31.07.2016
Zulvac 8 Bovis (EMEA/V/C/000145)	01.02.2016 – 31.07.2016
Zulvac 8 Ovis (EMEA/V/C/000147)	01.02.2016 – 31.07.2016
ZULVAC SBV (EMEA/V/C/002781)	01.03.2016 – 31.08.2016

- The Committee endorsed the list of products and calendar for signal detection analysis.

5.6 Supervision and sanctions

Information relating to supervision and sanctions will not be published as it would be undermining the purpose of such inspections.

The following document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee adopted the VICH guideline 54 on studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD) (EMA/CVMP/VICH/699251/2010), for implementation at step 7.
- The Committee endorsed the draft EU comments on draft 2 of the VICH guideline on stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV.

- The Committee endorsed the draft EU comments on draft 2 of the concept paper proposing a new VICH combination products guideline.
- The Committee endorsed the draft EU comments on group 2 proposals for the revision of the VICH anthelmintic guidelines 7, 11-16 and 19-21.
- The Committee endorsed the IWP proposal on how to proceed with the development of the draft VICH guideline on the use of cell cultures for the detection of extraneous agents in master seed viruses, master cell seeds and other starting materials of animal origin for mammalian veterinary virus vaccines, after considering the comments received on the EU proposal for a shortened VICH guideline.

6.2 Codex Alimentarius

- The Committee deferred the feedback on the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) meeting held on 17-21 October 2016 in Houston, USA, for the January 2017 CVMP meeting.

6.3 Other EU bodies and international organisations

- The Committee deferred the verbal report from the 2nd EMA/JECFA liaison meeting held on 26 September 2016 for the January 2017 CVMP meeting.
- The Committee endorsed comments on the JECFA draft guidance document for the establishment of acute reference dose (ARfD) for veterinary drug residues in food, to be forwarded to the JECFA secretariat.

The following document was circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 at this meeting cannot be released at the present time as it is deemed to be confidential.

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP-V procedures cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee received a verbal report from the chair of the SAWP-V on the meeting held on 6 December 2016, and noted the agenda of the meeting.
- The Committee discussed the nomination of a new member for the SAWP-V and noted the nominations received following the call for nominations.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the QWP veterinary vice-chair on the meeting held from 29 November to 1 December 2016, and noted the agenda of the meeting.
- The Committee adopted questions and answers on the removal of a general heavy metals test from a specification.
- The Committee adopted questions and answers on improving the understanding of normal operating ranges (NORs), proven acceptable ranges (PARs), design spaces (DSp) and normal variability of process parameters.

- The Committee discussed the draft concept paper on the need for revision of the note for guidance on quality of water for pharmaceutical use.

7.3 Safety Working Party (SWP-V)

- The Committee deferred the verbal report from the chair of the SWP-V on the meeting held on 23 November 2016 to the January 2017 CVMP meeting.
- The Committee discussed the guideline on assessing the toxicological risk to human health and the environment from veterinary pharmaceuticals in groundwater - *see also 7.4.*
- The Committee elected Eva Lander Persson as chair of the SWP-V for a further three-year mandate.
- The Committee endorsed the Veterinary Safety Curriculum of the EU Network Training Centre (EU NTC).

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the guideline on assessing the toxicological risk to human health and the environment from veterinary pharmaceuticals in groundwater - *see also 7.3.*

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the chair of the EWP-V on the meeting held on 29-30 November 2016, and noted the agenda of the meeting.
- The Committee adopted the concept paper for the revision of the guideline on veterinary medicinal products for zootechnical purposes (EMA/CVMP/EWP/707573/2015) for a 3-month period of public consultation.
- The Committee adopted the concept paper for the revision of the guideline on veterinary medicinal products for fluid therapy in case of diarrhoea (EMA/CVMP/EWP/707299/2015) for a 3-month period of public consultation.
- The Committee agreed to the involvement of AWP in the revision of the guideline on the summary of product characteristics (SPC) for antimicrobial products, following discussion of the comments received during the public consultation on the concept paper - *see also 7.6*.

7.6 Antimicrobials Working Party (AWP)

- The Committee agreed to the involvement of AWP in the revision of the guideline on the summary of product characteristics (SPC) for antimicrobial products, following discussion of the comments received during the public consultation on the concept paper - *see also 7.5*.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the Annex 2 to the revised CVMP guideline on requirements for the production and control of immunological veterinary medicinal products: the approach to demonstrate freedom from extraneous agents as part of the production and control of immunological veterinary medicinal products for mammalian species and finfish (EMA/CVMP/IWP/206555/2010), and the overview of comments received (EMA/CVMP/IWP/74071/2016). The Committee also adopted the CVMP reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products (EMA/CVMP/IWP/251741/2015), and the overview of comments received (EMA/CVMP/IWP/65876/2016).

- The Committee elected Esther Werner as chair of the IWP for a further three-year mandate.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a progress report on the PhVWP-V anti-parasitic sub-group activities and noted that the Committee would be informed of the outcome following conclusion of the exercise – *see also 5.5*.
- The Committee endorsed the Veterinary Pharmacovigilance Curriculum of the EU Network Training Centre (TC).
- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 22-23 November 2016, and noted the agenda and draft minutes of the meeting.
- The Committee received a verbal report from the chair of the PhVWP-V on the focus group meeting on promotion of pharmacovigilance for food producing animals, held on 23 November 2016, and noted the agenda of the meeting.
- The Committee elected Lisbet Vesterager Borge as chair of the PhVWP-V for a three-year mandate.
- The Committee was informed of the upcoming election of the vice-chair of the PhVWP-V for a 3-year term at the January 2017 CVMP meeting. *Post meeting note – the election is foreseen for the February 2017 CVMP meeting.*

7.9 Novel therapy groups and related issues

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG-3Rs)

- The Committee received a verbal report from the chair of the JEG-3Rs on the meeting held on 18-19 October 2016.
- The Committee adopted the revised mandate, objectives and rules of procedure for the joint CVMP/CHMP working group on the application of the 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (J3RsWG) (EMA/CHMP/CVMP/JEG-3Rs/442724/2012).
- The Committee adopted the guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012).

7.11 Other working party and scientific group issues

- The Committee adopted the revised guidelines on data requirements for veterinary medicinal products intended for minor use or minor species:

  - Quality (EMA/CVMP/QWP/128710/2004) and overview of comments (EMA/CVMP/QWP/472725/2016);
  - Safety (EMA/CVMP/SWP/66781/2005) and overview of comments (EMA/CVMP/SWP/523387/2016);
  - Efficacy (EMA/CVMP/EWP/117899/2004) and overview of comments (EMA/CVMP/EWP/523421/2016).

- The Committee adopted the work plans for 2017 for the CVMP working parties: SAWP-V (EMA/CVMP/SAWP/556760/2016), Joint CHMP/CVMP QWP (EMA/CHMP/CVMP/QWP/601201/2016), EWP-V (EMA/CVMP/EWP/507485/2016), IWP (EMA/CVMP/IWP/361742/2016), SWP-V (EMA/CVMP/SWP/616169/2016), ERAWP

(EMA/CVMP/ERA/373102/2016), J3RsWG (EMA/CHMP/CVMP/JEG-3Rs/647540/2016), AWP (EMA/CVMP/AWP/587904/2016) and PhVWP-V (EMA/CVMP/PhVWP/453416/2016) as well as for ADVENT (EMA/CVMP/ADVENT/500091/2016).

The following document was circulated for information:

- Minutes of the SAWP-V meeting held on 8 November 2016.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential.

- There were no items for discussion.

8.2 Environmental risk assessment

8.3 Antimicrobial resistance

- The Committee adopted (28 members in favour out of the 32 members present of those eligible to vote) the joint scientific opinion (EMA/EFSA) of the RONAFA Advisory Group on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU (EMA/570771/2015). The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. K. Baptiste, P. Hekman, G. Kulcsar and G. J. Schefferlie signed divergent positions not supporting parts of the aforementioned recommendation.
- The Committee received a verbal report on the EC request for a joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals.

8.4 Pharmacovigilance

- There were no items for discussion.

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to contain commercially confidential information.

- There were no items for discussion.

The following documents were circulated for information:

- The OIE strategy on AMR and the prudent use of antimicrobials;
- Evaluation of the action plan against the rising threats from antimicrobial resistance 2011-2016; executive summary.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for Community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee adopted the implementation plan for the centralised procedure for the QRD template version 8.1 (EMA/CVMP/757903/2016), which is foreseen to be published on the EMA website at the same time as the QRD template v.8.1 early in 2017.
- The Committee adopted the new QRD template for combined labelling & package leaflet for use during a 18-month pilot use (EMA/QRD/760520/2016). The document will be published on the section of the Agency's website relating to product information templates.
- The Committee endorsed the post authorisation guidance on change in classification. The guidance will be published on the EMA website.

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- The Committee noted the draft minutes of the meeting held on 10-11 November 2016 as well as the draft agenda of the meeting held on 8-9 December 2016.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the public CVMP work plan for 2017 (EMA/CVMP/450884/2016).
- The Committee adopted the revised scientific overview template guidance for immunological products:

  - Part 1 - Introduction;
  - Part 2 - Quality;
  - Part 3 - Safety;
  - Part 4 - Efficacy;
  - Part 5 - Benefit-Risk.

- The Committee deferred the discussion on the practical guidance document for CVMP members on CVMP operation and procedures for the January 2017 CVMP meeting.
- The Committee deferred the break-out session on the appointment of rapporteurs for CVMP procedures to the January 2017 CVMP meeting.
- The Committee noted the updated policy on handling of competing interests of scientific committees' members and experts.

13. LEGISLATION

14. ANY OTHER BUSINESS

- Upon the completion of the December 2016 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the December 2016 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
AT	Barbara Zemann	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 3.3 ProZinc (EMEA/V/C/002634/II/0010/G) • 5.5 PSUR for ProZinc • 10.2 one item
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Ljiljana Markuš-Cizelj	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 3.3 ProZinc (EMEA/V/C/002634/II/0010/G)
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stanko Srčič	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	Full involvement	
IS	Jóhann Lenharðsson	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FI	Kristina Lehmann	Full involvement	
FR	Sylvie Louet	Full involvement	
LT	Laimis Jodkonis	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SI	Katarina Straus	Full involvement	
SK	Eva Chobotová	Full involvement	
UK	Noemi Garcia del Blanco	Full involvement	
NO	Tonje Høy	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were only evaluated against the topics they have been invited to talk about.			
BE	Sandy Vermout - *remotely*	Full involvement	
DE	Ina Ebert	Full involvement	
DE	Silke Hickmann	Full involvement	
DE	Wolfgang Koch - *remotely*	Full involvement	
DE	Jens Schönfeld - *remotely*	Full involvement	
DK	Maria Krog Pedersen - *remotely*	Full involvement	
ES	Ricardo Carapeto Garcia	Full involvement	
ES	Sonia Gil Morales	Full involvement	
NL	Anita Bottger - *remotely*	Full involvement	
NL	Jacqueline Poot - *remotely*	Full involvement	
SI	Boris Kolar - *remotely*	Full involvement	
UK	Suzanne Eckford - *remotely*	Full involvement	
UK	Rutendo Manyarara - *remotely*	Full involvement	
UK	John Mitchell - *remotely*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes

CVMP working parties and CMDv	Chair
CMDv	--
ERAWP	Jason Weeks
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström
QWP	Mary O'Grady *(Vet vice chair) - remotely*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

Other observers		
Swissmedic	Beat Gassner - *remotely*	
Swissmedic	Stefan Herli - *remotely*	
Swissmedic	Rolf Hotz - *remotely*	
Swissmedic	Cordula Landgraf - *remotely*	
Swissmedic	Madeleine Meusburger - *remotely*	
FR	Jean-Pierre Orand	

European Medicines Agency support
Meeting run with relevant support from the EMA staff